

# APV Interactive Workshop on ATMP

## “Bridging standard pharma concepts and ATMP”



27 to 28 September 2018  
Vienna, Austria

Course no. 6743



### Target Audience:

Management of small and medium sized enterprises and experts from development, manufacturing and quality control in pharmaceutical industry involved in the process development and strategic planning necessary for market access of an Advanced Therapy Medical Products (ATMP).



Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik e.V.  
Gemeinnütziger wissenschaftlicher Verein  
International Association for Pharmaceutical Technology



A workshop organised by the focus group Pharmaceutical Biotechnology

## Summary of workshop contents

The workshop will focus on Advanced Therapy Medical Products (ATMP) as products in development for market supply. Speakers will share background knowledge gained during strategic planning and pharmaceutical development of designated non-orphan drugs. In the afternoon session of the first workshop day three round table discussions each headed by two to three experts will provide a platform for the participants to discuss their own topics, issues and strategy in an interactive manner. Results from these round tables will afterwards be taken together and presented to the audience.

## Goals and objectives

Share background knowledge for pharmaceutical and strategic development of Advanced Therapy Medical Products (ATMP).

The workshop will exclusively provide the combination to share background knowledge supportive for market access of ATMP and to discuss questions about own product portfolio.

## Organizer

**Chrisitan Ullrich**  
Repairon GmbH, Germany

**Hans-Georg Eckert**  
Valicare GmbH, Germany

## Chair/Co-Chair

**Ralf Sanzenbacher**  
Paul-Ehrlich-Institut, Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel, Germany

## Programme

**Thursday, 27 September 2018, 09:00 to 18:00**

### **Development and commercialization aspects of cellular immunotherapies**

Kai Pinkernell, Medigene

### **Marketability of ATMPs**

Zaklina Buljovicic, Pharmalex

### **Current regulation and future perspectives**

Ralf Sanzenbacher, Paul-Ehrlich Institut

### **The revised EU clinical trial regulations for medicinal products and medical devices**

Heiko von der Leyen, HCTC-KKS - Coordinating Center for Clinical Studies, MHH

### **Raw Materials for ATMP Manufacturing - Quality, regulatory and supply issues.**

Bernd Leistler, CellGenix

*Lunch break*

### **Round tables: Discussion with Q&A option**

#### **A) Role of future of hospital exemption and marketing authorization**

Ralf Sanzenbacher/Zaklina Buljovicic

Topics:

- IMPD, content of dossier and filing strategies
- Fast track approaches/Hospital exemption as a strategy to speed up market entry
- How different is the CMC and clinical development of an ATMP and a traditional biologics

#### **B) Processes & Automation (Co-Chair)**

Klaus Kühlcke/Christoph Peter

Topics:

- Manufacturing processes – the right decision at the right time
- Technical solutions and automation strategies
- Handling and quality requirements for in silico information

### **C) Specific CMC aspects of ATMPs**

Bernd Leister/Christian Ullrich/Hans-Georg Eckert

Topics:

- Quality topics and risk management
- Quality assays
- Pharmacopeia contents

Presentation and discussion of Round tables results

**Networking dinner**

**Friday, 28 September 2018, 08:30 to 13:00**

**ATMP manufacturing processes – the right decision at the right time**

Klaus Kühlcke, BioNTech IMFS

**Improved design of ATMP manufacturing processes**

Ulrike Köhl, MHH

**Formulation challenges of cell and gene therapy products**

Magdalena Obarzanek-Fojt, Novartis

**Establishing automated GMP production of ATMPs – hints and hurdles**

Christoph Peter, BioNTech AG

**Tumor vaccines - strategies for market supply**

Speaker to be confirmed

Programme subjected to be changed

## Location

IntercityHotel Wien  
Mariahilfer Str. 122  
A-1070 Wien  
Austria  
Phone: +43 1 525 85 0  
Fax: +43 1 525 85 111

I herewith repealable authorise APV to use my E-mail address to send me APV relevant material including current programme information. My acceptance can be cancelled at any time in writing.

## Date

Course no. 6743  
from 27 September 2018 09:00  
to 28 September 2018 13:00

## Registration fee

Industry 1490 EUR  
Academia/Authorities 745 EUR  
Student\* 178 EUR

(free of VAT according to § 4,22 UStG)

Coffee breaks, lunch, dinner and electronic proceedings included.

\*Limited places for full time students available; written evidence must be submitted.

## Registration

APV-Geschäftsstelle  
Kurfürstenstraße 59  
55118 Mainz/Germany  
Phone: +49 6131 9769-0  
Fax: +49 6131 9769-69  
e-mail: apv@apv-mainz.de

You will receive a confirmation of your registration with the invoice.

## Hotel reservation

IntercityHotel Wien  
Mariahilfer Str. 122  
A-1070 Wien  
Austria  
Phone: +43 1 525 85 0  
Fax: +43 1 525 85 111

Participants should make their own hotel reservation referring to the APV seminar.

Deadline for special conference rate: 29 August 2018

Special rate:  
Single room incl. breakfast buffet from 115,00 EUR per night.

Mainz, April 2018

## APV Interactive Workshop on ATMP, 27 - 28 September 2018, AT - Vienna, Course no. 6743

### Registration

As soon as you have found a seminar of your interest, it is very easy to register for it via fax, e-mail or online. We will process your registration promptly and certainly are available for any questions that may arise.

### Registration confirmation

After your registration was successfully processed, you will receive a confirmation.

### Before the event

A few days before the event starts, you will receive important information about the seminar, such as time, date, addresses etc.

### After the event

You will receive a certificate confirming your participation. Furthermore, we would like to ask you to fill-in our evaluation sheet to make sure we get better every time.

### Follow-up

After the event, we are open to receive any suggestions and critique that might arise during the seminar and will certainly help you with further questions you may have.

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International Association for Pharmaceutical  
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